

October 26, 2000

Honorable Donna Shalala Secretary of Health and Human Services 200 Independence Avenue, S.W. Room 615F Washington D C 20901

Dear Secretary Shalala:

As a small business owner and hearing health care provider, I write with respect to hearing aids. As the AARP has confirmed, hearing aids are highly effective but dramatically underutilized medical devices.

I am very concerned with reports that the Food and Drug Administration (FDA) has reportedly sent to you a proposal for revising the current regulations governing the dispensing of hearing aids in this country that would dramatically increase the cost of hearing health care services and restrict access to hearing health care providers. Additional cost will occur for patients, Medicaid, Medicare, and variety of insurance companies. This will cause premiums to increase for everyone. Please stop and carefully consider the impact that this proposed rule would have on the nation's hearing impaired and on the nation's small business hearing aid specialists. In particular, please ensure that any proposed rule meets the obligations of the Small Business Regulatory Enforcement Fairness Act.

Hearing impairment is a major health care concern. <u>Please don't let the FDA put forth their proposed rule that would impede access to needed hearing health care services for millions of Americans.</u>

Very truly yours,

Middia Patterson

Victoria B. Patterson, NBC-HIS

National Board Certified

Hearing Instrument Specialist

P.S. This will effect the right for me to earn an honest living as Hearing Healthcare Professional. Do not deny me that right please.

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